

CALIFORNIA ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF ENVIRONMENTAL HEALTH HAZARD ASSESSMENT
SAFE DRINKING WATER AND TOXIC ENFORCEMENT ACT OF 1986

**NOTICE OF MODIFICATIONS TO
TEXT OF PROPOSED REGULATIONS**

**TITLE 22, CALIFORNIA CODE OF REGULATIONS
SECTION 12805**

OAL RULEMAKING FILE No. Z-05-0614-06

**[Proposition 65 Maximum Allowable Dose Level (MADL) for Reproductive Toxicity
for Di(2-ethylhexyl)phthalate (DEHP) by Oral Exposure]**

May 5, 2006

Pursuant to the requirements of Government Code section 11346.8(c), Title 1, section 44 of the California Code of Regulations, the Office of Environmental Health Hazard Assessment (OEHHA) is providing notice of changes made to the proposed regulations, Title 22, California Code of Regulations, section 12805. These proposed regulations were originally the subject of a Notice of Proposed Rulemaking issued on June 24, 2005. A public hearing was held on August 8, 2005. Written and oral testimony was accepted at the hearing. In addition, written comments were received during the 45-day public comment period that ended on August 8, 2005.

This modification of text addresses an issue that was raised by the Office of Administrative Law (OAL) in its review of a similar regulatory proposal, the proposed maximum allowable dose levels (MADLs) for DEHP by the intravenous (iv) route. On December 13, 2005, OAL disapproved the proposed iv MADLs for DEHP regulation in part for failing to comply with the "clarity" standard required by the Administrative Procedure Act. OAL noted in its rejection that the age groups for neonatal boy and infant boy specified in the regulations did not have a meaning generally familiar to those directly affected, and that the terms were defined neither in the regulation nor in the governing statute. OAL also noted that the proposed MADLs did not show levels applicable to ages between infant and adult.

OEHHA addressed these issues for the iv MADLs by renaming "neonatal" as "neonatal infant," by specifying ages for "neonatal infant" and "infant," and by providing guidance for calculation of MADLs for males in the age groups between infant and adult. The regulatory process has since been completed and these changes for the iv MADL are currently being reviewed by the Office of Administrative Law for approval of adoption in regulation at a future date. OEHHA has modified the text of the proposed MADL

regulation for DEHP by the oral route in the same manner. In addition, OEHHA has correspondingly updated its support document "Proposition 65 Maximum Allowable Dose Level (MADL) for Reproductive Toxicity for Di(2-ethylhexyl)phthalate (DEHP) by Oral Exposure" to reflect and explain these changes. No other substantive modification was made to this document.

This notice announces the availability of the modified proposed regulatory text and supporting document for public comment. Comments regarding the proposed changes to the text of regulations, or the inclusion of the specified document, will be accepted by OEHHA between **May 5, 2006 through May 22, 2006**. All written comments must be submitted to OEHHA by e-mail, mail, fax, courier or hand-delivery, no later than 5:00 p.m. on **May 22, 2006**, and addressed to:

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Comments transmitted via email should be addressed to: sluong@oehha.ca.gov.

It is requested but not required that written statements or arguments be submitted in triplicate.

A copy of the revised proposed regulatory text is attached. The original proposed text that was not amended is shown in single underline. Amendments to the proposed text are shown in double-underline or single strike-out. The revisions to the supporting document "Proposition 65 Maximum Allowable Dose Level (MADL) for Reproductive Toxicity for Di(2-ethylhexyl)phthalate (DEHP) by Oral Exposure" are shown in single-underlined or strike-out. Inquiries concerning the action described in this notice may be directed to Susan Luong, in writing, at the address given above, or by telephone at (916) 445-6900.